

**REMARKS/ARGUMENTS**

In the Office Action dated September 22, 2004 claims 8-14 were examined with result that all claims were rejected. The Examiner made the rejection final. In response to the final rejection, applicant has filed a Request for Continuing Examination (RCE) together with an Amendment rewriting claim 8. Claim 10 has also been amended to correct a minor typographical error noted in a proofreading thereof. In view of the above amendments and following remarks reconsideration of this application is requested.

In the Office Action, claims 8-14 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner objected to the word "some" found in claim 8 as being a relative term. In response, applicant has canceled the phrase "some or" from claim 8 so that claim 8 now requires replacing all inorganic phosphorus. Applicant believes the Examiner should now withdraw the §112, second paragraph rejection.

Before turning to the substantive rejections, applicant would also like to briefly discuss the additional amendments made to claim 8. More specifically, claim 8 has been amended to limit the method to "lactating" dairy cows. Support for this amendment can be found in the specification as filed at page 11, lines 1-9.

In addition, claim 8 has been rewritten to include the phrase "an effective amount of" a 1 $\alpha$ -hydroxylated vitamin D compound. This was necessary to clarify the claim so that one would not read into this method step that the amount of vitamin D compound to be added would be equal to the amount of inorganic phosphorus removed in terms of weight percent. Clearly, the amount of vitamin D compound to be used would not be equal by weight percent to the amount of inorganic phosphorus replaced in the diet of a dairy cow, and this amendment merely clarifies that feature in claim 8. Support for this amendment can be found in the specification as filed for example at page 5, lines 14-15 and page 5, lines 26-27 as well as page 6, lines 9-11. Thus, applicant believes the addition of this phrase is not new matter. In addition, the Examiner should note that the "effective amount" is further defined in claim 10 as being from about 0.1 $\mu$ g/kg to about 100 $\mu$ g/kg of diet.

Turning now to the substantive rejections, claims 8-10 and 12-14 were rejected under 35 U.S.C. §102(b) as being anticipated by DeLuca et al. WO 96/24258. Applicant, however respectfully disagrees for the following reasons.

WO 96/24258 is directed solely to the increased utilization of phytate phosphorus, i.e. organic phosphorus, and not increased utilization of phosphorus from inorganic sources. Applicant refers the Examiner to applicant's previous arguments made in the Amendment dated June 24, 2004. The Examiner, however, has deemed these arguments unpersuasive, and refers to the Abstract of WO 96/24258 for support for the Examiner's position that this reference does teach the utilization of phosphorus from inorganic sources. Applicant disagrees with the Examiner since although the Abstract does refer to reduction of supplemental inorganic phosphorus due to the use of vitamin D compounds, it does so only in the context that vitamin D compounds increase utilization of phosphorus from the phytate complex. In other words, reading the Abstract in context, it is saying that vitamin D compounds cause improved utilization of phosphorus in animal feed with the result that supplemental quantities of phosphorus can be minimized or eliminated in the animal's diet. It is important to note that the first portion of the sentence refers an to animal feed whereas the second portion of the sentence refers to an animal's diet. Animal feed refers to a protein containing organic meal which is typically composed of corn, soybean meal or a corn/soybean mix. See for example, applicant's description at page 10, lines 3-6. On the other hand, the word "diet" implies everything that an animal might eat, and would include not only the organic meal but also inorganic phosphorus contained in feed supplements. Thus, applicant believes the Examiner is incorrectly reading the scope of the Abstract of WO 96/24258. The Abstract basically states that using vitamin D compounds to improve utilization of phytate phosphorus would result in the need to add less supplemental quantities of inorganic phosphorus since more organic phosphorus is being utilized as a result of the vitamin D compounds. Thus, applicant believes that the entire disclosure and description set forth in WO 96/24258 is in fact directed toward utilization of phosphorus in phytate complexes, and there is nothing

in this reference that teaches or suggests that  $1\alpha$ -hydroxylated vitamin D compounds could be used to increase utilization of phosphorus from inorganic sources. Thus, applicant believes the Examiner should withdraw the objection of claims 8-10 and 12-14 as being anticipated by WO 96/24258.

In the Office Action, claims 1 and 12-13 were rejected under 35 U.S.C. §102(b) as being anticipated by DeLuca et al. U.S. 4,338,312. Applicant however, respectfully disagrees for the following reasons.

The DeLuca '312 patent discusses the feeding of high calcium and low phosphorus diet to cows "in the dry period" and throughout the parturition portion of the experiment. Upon successful calving, the "treatment was discontinued." This clearly and unambiguously means that the vitamin D compound was no longer being administered to the cow. The Examiner is referred to the example of Col. 3, lines 15-26. Thus, in the '312 patent, the  $1\alpha$ -hydroxylated vitamin D compound was given to the cow immediately prior to and during calving i.e. what is referred to the "dry period" of dairy cows. During this dry period the dairy cows are not lactating and are thus not producing milk. As a result, it would not be possible to determine whether the  $1\alpha$ -hydroxylated vitamin D compound given in the experiment of the '312 patent would "maintain milk production" as required by present claim 8, since there is no milk production in the period in which the compound was administered to the cow. In addition, claim 8 requires the administration of the vitamin D compound to a lactating dairy cow. None of the cows in the DeLuca '312 patent were lactating. Finally, claim 8 calls for replacing all inorganic phosphorus in a diet for a dairy cow. In the DeLuca '312 patent, the cows are on a low phosphorus diet, and thus there is no teaching or suggestion in the '312 patent that one could replace all inorganic phosphorus. Thus, DeLuca '312 cannot anticipate the claimed invention. Further, the '312 reference cannot render the presently claimed invention obvious since there is no suggestion to one skilled in the art that the administration of  $1\alpha$ -hydroxylated vitamin D compounds would maintain milk production in a dairy cow.

The Examiner argues that the DeLuca '312 patent discloses a method for prophylactically treating dairy cows for parturient paresis wherein the instant compounds are administered and refers to claims 1 and 3 to find support for the Examiner's conclusion that the DeLuca '312 inherently will maintain milk production in a dairy cow fed a low phosphorus diet as claimed via present claim 8. However, one must look at a reference for what it fairly teaches, not what the claims may potentially cover. The '312 patent does not teach or suggest a method for maintaining milk production in a dairy cow wherein all of the inorganic phosphorus typically fed to a dairy cow is replaced with a  $1\alpha$ -hydroxylated vitamin D compound. There is simply nothing in the '312 reference which teaches or suggests what is called for in claim 8. The cows treated in '312 are not lactating dairy cows, and the "low phosphorus" diet fed to the cows in the '312 reference in fact contains phosphorus. The present claims, however, require feeding lactating dairy cows and require replacing all of the inorganic phosphorus with an effective amount of a  $1\alpha$ -hydroxylated vitamin D compound. Neither of these features can be found anywhere, either explicitly or inherently in the teachings of the '312 reference.

In the Office Action, claims 1 and 12-13 were rejected under 35 U.S.C. §102(b) as anticipated by DeLuca et al. U.S. 4,110,446. Once again, the Examiner alleges that the teaching in the '446 patent inherently discloses the present invention of claim 8.

In response, and for the same reasons noted above, it is clear that the '446 reference is once again referring to the "dry period" of dairy cows. As the Examiner can see from what is taught in the '446 reference, a solution of  $1\alpha$ , 25-dihydroxylated vitamin D3 was given to dairy cows about five days prior to predicted calving. See Col. 4, lines 2-16. The '446 reference concludes that Col. 5, lines 10-17 that treatment with  $1\alpha$ , 25-dihydroxylated vitamin D3 is particularly effective during the critical period from about 24 hours pre- to 48 hours post-calving to prevent milk fever disease. Thus, it is clear that the compound  $1\alpha$ , 25-dihydroxylated vitamin D3 is not being administered to lactating dairy cows. Instead, it is being administered immediately prior to calving and during the dry period of dairy cows.

Further, it should be noted that the dairy cows received a diet containing greater than 100 grams calcium and less than 45 grams phosphorus daily (see Col. 4, lines 9-12). A diet containing about 45 grams of phosphorus is not one wherein all inorganic phosphorus was replaced by the vitamin D compound, as now called for by claim 8. Thus, applicant believes that the '446 reference does not anticipate or render obvious applicant's claims.

In the Office Action, claims 9-11 were rejected under 35 U.S.C. §103(a) as being unpatentable over DeLuca '312 and DeLuca '446. The Examiner's position is that it would be obvious to optimize the amount of vitamin D compound given to a dairy cow.

Applicant believes, however, that neither of these references anticipate or render obvious claim 8, as now amended, and as discussed above. In addition, applicant believes that neither of these references disclose that a diet can include 0% by weight of an inorganic phosphorus supplement as called for by claim 11.

Finally, the Examiner states that the data presented in applicant's specification do not provide clear and convincing evidence of nonobviousness or unexpected results over the cited prior art. Instead, the Examiner believes they present expected results based on the prior. However, neither the '312 nor the '446 reference discloses the ability of vitamin D compounds to replace all of the inorganic phosphorus in a cow's diet while at the same time not affecting milk production in lactating dairy cows. There is clearly no discussion or suggestion to use a diet containing no inorganic phosphorus in combination with a vitamin D compound on a regular basis as part of the daily diet of a dairy cow. Again, neither of these references discuss the effects of a low phosphorus diet in combination with a vitamin D compound on milk production. Thus, applicant fails to see how either reference teaches or suggests that such a combination may be used to eliminate phosphorus in the diet of an animal feed via the administration of a vitamin D compound on a regular basis as part of the daily diet for such animals.

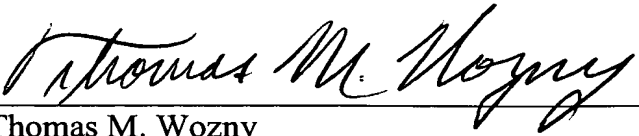
Application No. 09/815,573  
Amendment Dated December 22, 2004  
Reply to Office Action of September 22, 2004

An effort has been made to place this application in condition for allowance  
and such action is earnestly requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By

A handwritten signature in cursive script, reading "Thomas M. Wozny", written over a horizontal line.

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